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DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
300 Pearl Street, Suite 100
Buffalo, NY 14202

May 19, 2004

WARNING LETTER NYK 2004-16

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

Perry T. Dewey, Owner
Perry Dewey Farm
8827 French Creek Road
Clymer, NY 14724

Dear Mr. Dewey:

An investigation performed by U.S. Food and Drug Administration Investigator Linda M. Sacco included an inspection of your dairy farm on April 6, 15, & 20, 2004. The investigation confirmed you offered two cows for sale for slaughter as food in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

In late July or early August, 2003 two dairy cows, one bearing farm tag 52 and the other bearing farm tag 59, were administered [REDACTED] a gentamicin-containing drug product, on your farm. Both cows were administered 10 cc infusions of [REDACTED] twice a day, into each infected quarter, for a period of four to five days. Both cows were subsequently offered for sale for human food through [REDACTED], and both were subsequently sold to [REDACTED].

USDA analysis of samples collected on October 31, 2003 at [REDACTED] identified the presence of 06.72 ppm gentamicin in kidney tissue and 00.12 ppm gentamicin in liver tissue collected from the cow bearing farm tag 52. USDA analysis of samples collected on November 14, 2003 at [REDACTED] identified the presence of 00.57 ppm gentamicin in kidney tissue from the cow bearing farm tag 59.

There is no permitted level for residues of gentamicin in edible tissues of cattle. The presence of this drug in kidney and liver tissue of these animals causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

Our investigation also found you hold animals under conditions whereby medicated animals bearing potentially harmful drug residues are likely to enter the food supply. You lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in the labeling, and for assuring that animals medicated on your farm have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. For example, you lack adequate written treatment records for veterinary drugs administered to your herd. Such records would identify the drugs administered, the treatment date, identification of the animal treated, the dosage administered, the route of administration, the individual administering the medication, and the withdrawal times for milk and beef. Food from animals held under such conditions is adulterated within the meaning of Section 402(a)(4) of the Act.

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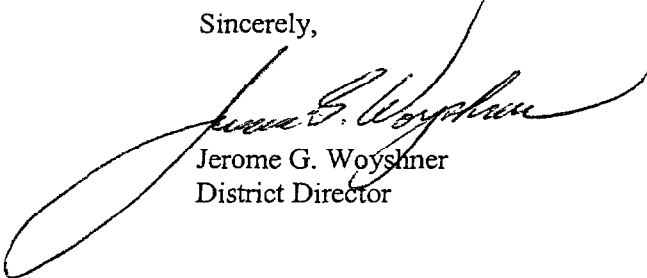
You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice. This may include seizure or injunction.

In addition, you caused the veterinary drug [REDACTED] to become adulterated within the meaning of Section 501(a) (5) of the Act. Gentamicin-containing drug products are not approved for use in lactating dairy cows.

This letter is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law. It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Federal Food, Drug and Cosmetic Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

Please notify this office in writing, within 15 days, of the steps you have taken to prevent a recurrence of similar violations. Your response should be directed to James M. Kewley, Compliance Officer, at the above address.

Sincerely,



Jerome G. Woyshner
District Director

cc: Ted R. Dewey, Herdsman
Perry Dewey Farm
8827 French Creek Road
Clymer, NY 14724